

EXHIBIT 7

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UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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UNITED STATES OF AMERICA
ex rel. JULIE LONG,
Plaintiffs,

vs.

JANSSEN BIOTECH, INC.,
Defendant.

Civil Action No.: 16-12182-FDS

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VIDEOTAPED DEPOSITION OF THOMAS CORNELLY
Friday, December 15, 2023
Conducted Remotely

REPORTED BY:
Christina Diaz, CRC, CRR, RMR, CSR-NY/NJ, CLR
HUDOSN COURT REPORTING & VIDEO (800) 310-1769

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December 15, 2023
8:39 A.M. E.S.T.

Videotaped deposition of THOMAS
CORNELLY, taken by plaintiffs, pursuant to
notice dated November 29, 2023, conducted
remotely, before Christina Diaz, a Certified
Realtime Captioner, Certified Realtime and
Registered Merit Reporter and Notary Public
within and for the State of New York.

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A P P E A R A N C E S (Cont'd.)

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ALSO PRESENT:
EDWIN MENDEZ, Videographer

Pages 1 to 4

1 T. Cornely
 2 obviously off label is something that's not
 3 provided by our reps, yes.
 4 Q. Going back to the issue of how
 5 you would evaluate further, if there was a
 6 concern about value or monetary value,
 7 would you go and confer with anybody else
 8 in that evaluation, or was that something
 9 you did on your own?
 10 MR. RAOFIELD: Objection to the
 11 form of the question.
 12 A. Hard to say whether it was black
 13 and white. It would be something -- if
 14 there was ever questions, we could discuss
 15 it with my director. But the number one
 16 thing we'd look at is the policy, and then
 17 if it became something that was evaluated
 18 against the policy and it was anything that
 19 we needed -- further evaluation or more
 20 experience or general consulting, I could
 21 absolutely talk to my director or other HCC
 22 officers.
 23 It wasn't done in a vacuum. It
 24 was looked at, first, the policy, and then
 25 what did the policy say. And if there was

1 T. Cornely
 2 any sort of discussion about that
 3 particular document, we would -- you could
 4 talk about it with others. But without
 5 being too specific, I don't know what would
 6 -- and not remembering what exact documents
 7 we talked more about.
 8 Q. Was there ever a time where the
 9 box was checked, yes, regarding potential
 10 value or monetary value being a concern for
 11 a service where you went and conferred with
 12 the legal department?
 13 MR. RAOFIELD: Hold on one
 14 second.
 15 A. Can you repeat that?
 16 MR. RAOFIELD: Yes, just give me
 17 one second.
 18 THE WITNESS: Okay.
 19 MR. RAOFIELD: I think I'll allow
 20 the witness -- you might want to ask it
 21 again or read the question back, but I
 22 think the witness can answer, yes or
 23 no, whether he remembers that
 24 situation, a yes-or-no question.
 25 MR. RAZAVI: Sure.

1 T. Cornely
 2 BY MR. RAZAVI:
 3 Q. So going back to the same issue
 4 we've been talking about on page 7 of
 5 Exhibit 126 -- and I guess let me define.
 6 So this category, where it says, "Does the
 7 submission contain reimbursement/value
 8 proposition, access, consulting services
 9 and training or have any monetary value
 10 (HCC)?"
 11 What did you generally refer to
 12 that as when it's checked, yes? What did
 13 you call that in your own head, or if
 14 you're talking to Angela Wood, what was
 15 that box referring to?
 16 MR. RAOFIELD: Objection to form.
 17 Do you understand the question?
 18 A. I am trying to understand it. If
 19 this box was checked, it means that I have
 20 to check the content of this submission
 21 versus HCC policy and making sure it
 22 complies.
 23 BY MR. RAZAVI:
 24 Q. So this box is a triggering -- if
 25 it's checked, yes, is triggering a further

1 T. Cornely
 2 investigation by you as to whether the
 3 program or service is in compliance with
 4 HCC guidelines, correct?
 5 A. I wouldn't use the word
 6 "investigation." I would -- further
 7 review. It's part of the PRC review
 8 process.
 9 Q. Gotcha. Okay. Was there ever a
 10 time where your further review of this HCC
 11 compliance-type of issue led you to seek
 12 advice from the legal department, just yes
 13 or no?
 14 MR. RAOFIELD: Object to the form
 15 of the question.
 16 Instruct the witness not to
 17 disclose any communications that you
 18 may or may not have had with counsel.
 19 But you can answer, yes or no, whether
 20 you remember that particular situation
 21 happening, yes or no.
 22 A. Yes.
 23 BY MR. RAZAVI:
 24 Q. Was that something you would
 25 choose to do or something that either

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1 T. Cornely
 2 Angela or Erin would direct you to do?
 3 MR. RAOFIELD: Objection to form.
 4 A. Generally, to the best of my
 5 knowledge, I would do that.
 6 BY MR. RAZAVI:
 7 Q. Was this something you did with
 8 some frequency?
 9 MR. RAOFIELD: Hold on one
 10 second.
 11 So I think that you can answer
 12 that one still, but we, again, are
 13 getting very close to the line. And I
 14 want to emphasize that we are not
 15 asserting advice of counsel. We are
 16 not relying on advice of counsel. You
 17 understand our position. We're not
 18 asking the questions, you are. We're
 19 not putting anything into evidence.
 20 I'm just drawing the line now about
 21 what's an appropriate question to
 22 protect privilege versus what you're
 23 entitled to ask.
 24 And with all of that said, I
 25 think that that is still a question

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1 T. Cornely
 2 that would be consistent with something
 3 that would appear on a privileged log.
 4 And, on that basis, I will allow the
 5 witness to answer, yes or no.
 6 BY MR. RAZAVI:
 7 Q. Do you want me to re-ask it,
 8 Mr. Cornely?
 9 A. If you could, I appreciate it.
 10 MR. RAZAVI: Respectfully, we
 11 disagree with that objection.
 12 BY MR. RAZAVI:
 13 Q. You just testified that as part
 14 of the PRC process, when there was a
 15 concern raised about a program or service
 16 being in violation of HCC guidelines, as
 17 part of your further review, you would go
 18 and reach out to the legal department.
 19 Do you remember that question?
 20 MR. RAOFIELD: Objection to the
 21 form. Misstates prior testimony.
 22 THE WITNESS: I agree with that.
 23 BY MR. RAZAVI:
 24 Q. Do you recall that question?
 25 A. I would rephrase that.

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1 T. Cornely
 2 Q. Sure. Tell me the correct way.
 3 A. I could -- if there was a
 4 situation, not necessarily regarding HCC
 5 policy but a situation where legal -- more
 6 in the legal space required input, I would
 7 talk to the attorney that is on PRC.
 8 Q. Okay. So I want to limit it just
 9 to the HCC issues for the moment.
 10 A. Okay.
 11 Q. Again, looking at Exhibit 126,
 12 page 7, we talked about this box being
 13 checked regarding value and monetary value.
 14 And I asked how you would describe it, and
 15 you said that is a box that means you need
 16 to do further review to see if the program
 17 or service is in violation, or does it
 18 match up with HCC guidelines. Am I correct
 19 so far?
 20 A. "Complies with HCC policy," is
 21 the way I would put it.
 22 Q. Then I asked, would you go, as
 23 part of your further review of a concern of
 24 a program being in compliance with HCC
 25 guidelines, confer with your supervisor

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1 T. Cornely
 2 Angela or Erin at the time, and you said,
 3 yes, you would do that from time to time?
 4 A. From time to time.
 5 Q. And then I asked, Would you ever
 6 go and seek the advice of the legal
 7 department from time to time.
 8 Is that answer also, yes?
 9 MR. RAOFIELD: You can answer
 10 that, yes or no.
 11 A. I am just trying to think of the
 12 way it was phrased. Generally, yes.
 13 BY MR. RAZAVI:
 14 Q. Was this something -- I know it's
 15 going to be hard to quantify, but is this
 16 something you did with some frequency? Was
 17 it something that only happened once in
 18 your three years on the PRC? Was it
 19 something that happened every time? Can
 20 you give me some idea of the frequency by
 21 which you would confer with legal to
 22 address concerns you may have had with HCC
 23 compliance or services while you were a
 24 member of the PRC?
 25 MR. RAOFIELD: Objection to the

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1 T. Cornely
 2 That's a yes?
 3 A. Yes.
 4 Q. So my question to you is, was
 5 there ever a time where you reached out to
 6 the legal department to address a PRC
 7 compliance concern or question, and you
 8 disagreed with the response you received
 9 from the legal department?
 10 MR. RAOFIELD: I think I will --
 11 again, getting very close to the line
 12 here, but I think I will allow the
 13 witness to answer that question, yes or
 14 no. Let me just double-check by
 15 reading it.
 16 I think he can answer that one --
 17 again, we're -- I don't understand why
 18 we're dancing this dance with these
 19 difficult issues, but I think that one,
 20 my judgment is that he can say, yes or
 21 no.
 22 A. Okay. So you were asking, did I
 23 ever disagree with legal when during a
 24 discussion or consultation regarding a PRC
 25 material? Is that the question you're

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1 T. Cornely
 2 asking?
 3 BY MR. RAZAVI:
 4 Q. Yes.
 5 A. Okay. To the best of my
 6 knowledge or recollection as always,
 7 because it was a long time ago, I cannot
 8 recall disagreeing with legal.
 9 Q. Okay. If during a PRC
 10 evaluation, the medical affairs member
 11 disagreed with you or the legal member on
 12 the PRC about antikickback implications for
 13 a program or service, was their decision
 14 ever permitted to trump your own evaluation
 15 of whether that program was indeed in
 16 compliance?
 17 Do you understand my question?
 18 MR. RAOFIELD: Objection to the
 19 form of the question.
 20 MR. RAZAVI: Let me rephrase it.
 21 BY MR. RAZAVI:
 22 Q. If during a PRC meeting, the
 23 medical affairs personnel believed that a
 24 program was in compliance with HCC
 25 guidelines but the legal member or the HCC

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1 T. Cornely
 2 compliance member believed it was not in
 3 compliance with HCC guidelines, who got the
 4 final say?
 5 MR. RAOFIELD: Objection to the
 6 form of the question.
 7 A. From what I recall -- it sounds
 8 like, honestly, a hypothetical question to
 9 me, but I will tell you that I was
 10 responsible for reviewing and approving
 11 materials and making sure that they were in
 12 compliance with HCC policy; not any other
 13 function.
 14 BY MR. RAZAVI:
 15 Q. Okay. So now stepping back to
 16 when you would go and reach out to the
 17 legal department, were they the final say
 18 for any questions that you had regarding
 19 HCC compliance issues?
 20 MR. RAOFIELD: Objection to the
 21 form of the question, and caution the
 22 witness not to disclose any
 23 conversations with counsel.
 24 A. In that scenario, I honestly -- I
 25 don't recall if there was a situation where

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1 T. Cornely
 2 that came up.
 3 BY MR. RAZAVI:
 4 Q. In other words, it goes back to
 5 the last question we had about you
 6 disagreeing with counsel.
 7 So, for example, in the PRC
 8 meeting, if the medical affairs personnel
 9 said, Mr. Cornely, I disagree with your
 10 assessment of whether this program is in
 11 compliance with HCC guidelines, you would,
 12 I am sure, respectfully, say, well, look,
 13 this is my specialty. I am the one that
 14 makes the final determination. Correct?
 15 MR. RAOFIELD: Objection to the
 16 form of the question.
 17 A. There was never a discussion like
 18 that. This is very hypothetical at this
 19 point.
 20 We didn't sit over a table
 21 and argue whether -- the medical person
 22 did argue with me whether there is a
 23 violation of HCC policy. We all reviewed
 24 documents within our subject matter
 25 expertise.

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1 T. Cornely
 2 BY MR. RAZAVI:
 3 Q. And the expertise that you had
 4 was compliance with HCC guidelines,
 5 correct?
 6 A. I reviewed documents to make sure
 7 they were in accordance with HCC policy.
 8 Q. And when you had concerns about
 9 -- strike that.
 10 When you had questions about
 11 whether they were in compliance with HCC
 12 policy, and you would occasionally go to
 13 the legal department, were they the final
 14 say on that issue, or did you have the
 15 ability to deviate from whatever answer
 16 they gave back to you? And I don't want to
 17 know any specifics.
 18 Just yes or no?
 19 A. Yes.
 20 MR. RAOFIELD: Objection.
 21 Misstates his prior testimony again.
 22 A. In a scenario where I am having a
 23 discussion with legal, it's -- which I've
 24 said happened before, it was more for point
 25 of view. But ultimately --

1 T. Cornely
 2 MR. RAOFIELD: I am just going to
 3 caution the witness not to get into
 4 communications with counsel.
 5 THE WITNESS: Point of view.
 6 BY MR. RAZAVI:
 7 Q. Did you always follow point of
 8 view provided by legal counsel is all I am
 9 getting at.
 10 MR. RAOFIELD: Hold on a second.
 11 BY MR. RAZAVI:
 12 Q. I don't want to know what the
 13 point of view was. I just want to know in
 14 those circumstances where you would reach
 15 out to legal to question whether a program
 16 or service was HCC compliant, did you
 17 always follow the point of view provided to
 18 you by counsel?
 19 MR. RAOFIELD: I am going to
 20 object to form. And I have got to read
 21 this question carefully.
 22 And we have been going like an
 23 hour and twenty minutes. So I do want
 24 at some point to have a break here,
 25 but...

1 T. Cornely
 2 I am objecting. Once again, I
 3 think you have for the third time
 4 misstated his prior testimony. And you
 5 are now getting into very specific
 6 questions.
 7 MR. RAZAVI: Are you instructing
 8 him not to answer?
 9 MR. RAOFIELD: I am reading your
 10 question to try to figure out how I can
 11 allow him to answer something without
 12 getting any privilege.
 13 So I will allow the witness to
 14 answer -- and, again, this is just --
 15 it's absurd to me that we are spending
 16 so much time on this. I will allow the
 17 witness to answer whether he recalls
 18 that ever even happening, whether he
 19 recalls any such situation, yes or no.
 20 BY MR. RAZAVI:
 21 Q. In circumstances where you would
 22 reach out to legal to follow up as to
 23 whether a program or service was HCC
 24 compliant as part of your PRC process, did
 25 you always follow the point of view

1 T. Cornely
 2 provided to you by the legal department?
 3 Just yes or no?
 4 MR. RAOFIELD: And I am again
 5 going to say that that misstates his
 6 prior testimony pretty clearly.
 7 You can answer the question
 8 whether you recall any such thing ever
 9 happening.
 10 A. I can't recall.
 11 BY MR. RAZAVI:
 12 Q. Okay. Have I misstated your
 13 testimony?
 14 MR. RAOFIELD: Do you want to
 15 tell him what the --
 16 MR. RAZAVI: I will read back the
 17 question. I want to make sure I got it
 18 correctly.
 19 In circumstances where you would
 20 reach out to legal to follow up as to
 21 whether a program or service was HCC
 22 compliant as part of your PRC process,
 23 did you always follow the point of view
 24 provided to you by the legal
 25 department.

1 T. Cornely
2 PRC, is looked at to be sure it's in
3 accordance with HCC policy.
4 BY MR. RAZAVI:
5 Q. So it's your testimony -- well,
6 do you recall ever looking at a program or
7 service while on the PRC that you were
8 particularly concerned might be a violation
9 of HCC guidelines?
10 MR. RAOFIELD: Objection to form.
11 A. I don't recall.
12 BY MR. RAZAVI:
13 Q. What would cause you to seek out
14 -- strike that.
15 What would cause you to refer
16 back to the HCC guidelines while conducting
17 a PRC review? What's an example?
18 MR. RAOFIELD: Objection to form.
19 A. Do you want to know how I would
20 review something?
21 BY MR. RAZAVI:
22 Q. No. Earlier we asked what
23 resource would you go to if you had
24 questions about whether something was in
25 compliance, and you said I would look at

1 T. Cornely
2 the guidelines, right?
3 A. Yes, HCC policy, absolutely.
4 Q. So did you look at the HCC policy
5 every single Tuesday you were having a PRC
6 meeting?
7 A. I can't definitively say it was
8 every single Tuesday or every single PRC
9 document, but I would say -- in general, in
10 my job, for six years of being an HCC
11 officer, I would say that regardless of
12 whether it was PRC review or not, I opened
13 those policies probably anywhere from 90
14 percent plus at the time to review them on
15 a daily basis to make sure what everyone
16 was talking about, whether it was PRC or
17 whether it was a discussion -- or some
18 other area, I reviewed those policies all
19 the time.
20 Q. So if there was a proposed
21 program in front of you as a member of the
22 PRC regarding providing advice to
23 physicians about how to improve
24 profitability, would you ask the legal
25 member on the PRC their opinion about

1 T. Cornely
2 whether that program is compliant with the
3 applicable guidelines?
4 MR. RAOFIELD: Objection to the
5 form of the question. And I think I
6 have to instruct the witness not to
7 answer because you are now getting into
8 conversations with counsel.
9 MR. RAZAVI: I don't want to go
10 too far down this rabbit hole. Jason,
11 you can correct me if I am wrong, but I
12 thought in Zalesky's depo when we had
13 the back and forth, it was Janssen's
14 position that they were not waiving
15 attorney-client privilege outside of
16 the PRC, but they are permitting us to
17 discuss it within the PRC. So I am
18 trying to find out, is it just waiving
19 5 percent of the PRC attorney
20 privilege, or what's the position being
21 taken by Janssen?
22 MR. RAOFIELD: No. The position
23 -- I think what you are thinking of,
24 Poorad, was you were asking -- even
25 though you hadn't marked the SOPs,

1 T. Cornely
2 which would give you the information
3 that's not privileged, you were asking
4 about the function of the legal
5 reviewer on the PRC. And that was the
6 line I was attempting to draw was to
7 allow you to do that even though you
8 could have marked the exhibit and it
9 would have just told you, but the
10 actual conversations and the legal
11 advice that involves the legal members
12 of the PRC is privileged. So if that
13 wasn't clear, I hope it's clear now.
14 And I think earlier today, you
15 have asked questions that I have
16 asserted privilege over regarding
17 communications with PRC legal member.
18 MR. RAZAVI: Maybe this is an
19 off-line conversation. I guess I am
20 struggling to understand how Janssen
21 can rely on the approval of the PRC
22 without allowing us to examine
23 everything the PRC did.
24 MR. RAOFIELD: Because that's
25 what Judge Saylor found in an order

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1 T. Cornely
 2 that merely relying on a PRC process
 3 does not waive privilege, so that's our
 4 position.
 5 MR. RAZAVI: Okay. Agree to
 6 disagree. Okay.
 7 MR. RAOFIELD: As I have said
 8 many times, we are not putting in any
 9 of this. You keep asking all these
 10 questions. That's your choice to ask
 11 what you want. We are not putting in
 12 anything relating to reliance on
 13 counsel.
 14 MR. RAZAVI: I guess for the
 15 record, that's exactly what Janssen is
 16 doing, because their affirmative
 17 defense of good faith reliance on the
 18 PRC involves the advice of counsel that
 19 PRC legal member provided. I will let
 20 Janssen sell that to the court at the
 21 appropriate time, but agree to
 22 disagree.
 23 MR. RAOFIELD: Sure. I think
 24 what you just said was probably in your
 25 brief to Judge Saylor and he didn't

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1 T. Cornely
 2 agree, but, again, I don't think we
 3 need to waste any of your time on this.
 4 BY MR. RAZAVI:
 5 Q. As a compliance officer, did you
 6 ever do an analysis about what the term
 7 "practice management" meant?
 8 A. I don't recall if we ever did
 9 that.
 10 Q. Do you recall reviewing services
 11 involving practice management or the site
 12 of care programs from 2013 to 2016?
 13 A. I recall reviewing training and
 14 educational materials regarding site of
 15 care for ABSes to present promotionally.
 16 Q. Do you remember any of those
 17 involving practice management?
 18 MR. RAOFIELD: Objection to the
 19 form of the question.
 20 A. I do think there were some
 21 educational materials regarding practice
 22 management that were reviewed as part of
 23 the PRC process.
 24 BY MR. RAZAVI:
 25 Q. Do you recall ever rejecting any

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1 T. Cornely
 2 of those types of materials?
 3 A. I don't recall outright
 4 rejecting. I just don't. It was a while
 5 ago.
 6 Q. Do you recall if the legal member
 7 on the PRC ever rejected any practice
 8 management materials or SOC?
 9 MR. RAOFIELD: Objection to the
 10 form of the question, and instruct the
 11 witness not to answer on the basis of
 12 privilege.
 13 BY MR. RAZAVI:
 14 Q. Are you familiar with the phrase,
 15 "establishing a filtering process for the
 16 law department review of proposed
 17 product-related items and service
 18 offerings"?
 19 A. I am not.
 20 Q. The concept of filtering process,
 21 have you heard that in any way, shape, or
 22 form in the context of PRC or legal review?
 23 A. Not that I can recall.
 24 MR. RAZAVI: Let me show you
 25 Exhibit 119.

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1 T. Cornely
 2 (Exhibit 119 was referenced for
 3 identification)
 4 BY MR. RAZAVI:
 5 Q. This is Bates stamped JANSSEN BIO
 6 64-482. Just take a look at this and let
 7 me know when you have had a topical review
 8 of it.
 9 A. Okay. Give me a minute.
 10 Q. Sure.
 11 A. (Witness reviewing document).
 12 MR. RAOFIELD: Poorad, do you
 13 have any reason, metadata or otherwise
 14 to think that this was a document the
 15 witness saw, or are you just going to
 16 ask him if he ever saw it?
 17 MR. RAZAVI: Correct. Well. I
 18 am assuming he would have seen it, but
 19 maybe not. Maybe they don't share.
 20 MR. RAOFIELD: I just mean like
 21 his name on the document or in the
 22 metadata or some basis other than --
 23 because I didn't see it. I just wanted
 24 to make sure that there wasn't
 25 something you were aware of.

Pages 221 to 224